IS 12418-4 (2000): Intra-Uterine Contraceptive Devices, Part 4: Copper-T (200 B) [MHD 3: Obstetric and Gynaecological Instruments and Appliances]

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(Reaffirmed 2006)

भारतीय मानक

अन्तर्गर्भाशय गर्भनिरोधक युक्तियाँ — विशिष्टि

भाग 4 कापर-टी (200 बी)

(दूसरा पुनरीक्षण)

Indian Standard

INTRA-UTERINE CONTRACEPTIVE DEVICES — SPECIFICATION

PART 4 COPPER-T (200 B)

(Second Revision)

ICS 11.200

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 4

FOREWORD

This Indian Standard (Part 4) (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by Obstetric and Gynaecological Instruments and Appliances Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1987 at the instance of Ministry of Health and Family Welfare, Government of India and was revised in 1991 to bring it in line with the changes made by Population Council of USA in their specification. The present revision has been necessitated as a result of experience gained through its implementation by the Ministry of Health. This has also taken into consideration the difficulties faced by the Indian manufacturers either in the manufacturing or at testing stage. Problems faced by the gynaecologists while fitting the device have also been kept in mind.

Plastics, rubber, other polymers, metals, etc, are being increasingly used in various medical devices. Different materials used are covered under these broad categories. However, it is imperative to ensure that the type of raw material used in the manufacture of medical devices is such that it is free from any harmful effects on the body either on its own or in combination with others or after interaction with body tissues and fluids. It shall, therefore, be the responsibility of the manufacturers of a medical device to satisfy themselves of the biological compatibility of the materials used without causing undue allergic, toxic or inflammatory reaction in the human body. Materials used shall also be capable of withstanding prescribed sterilization process without any deterioration or effect.

Guidelines for Good Manufacturing Practices relating to Intra-Uterine Contraceptive Devices do not exist at present. Manufacturers should follow the guidelines provided by their collaborators or their own for Good Manufacturing Practices, for manufacturing these devices till the guidelines are formulated.

This device would be required to undergo extractables and implantation tests on animals and clinical trials on voluntary acceptors. This device has been declared as 'drug' by the Ministry of Health & Family Welfare (Department of Health) under the *Drugs and Cosmetics Act* 1940. Since the regulatory functions for ensuring conformity to this standard rest with the Drugs Controller General (India), BIS certification marking would not be applicable for this device.

This standard has been published in four parts. Other parts of the standard are:

Part 1 General requirements
Part 2 Determination of breaking force
Part 3 Packaging and labelling

There is no ISO/IEC standard on the subject. In the formulation of this standard, assistance has been derived from the specification on Copper-T prepared by the Population Council of USA.

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For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

INTRA-UTERINE CONTRACEPTIVE DEVICES — SPECIFICATION

PART 4 COPPER-T (200 B)

(Second Revision)

1 SCOPE

1.1 This standard (Part 4) covers the shape, dimensions and other requirements for intra-uterine contraceptive device, Copper-T (200 B) and its components.

2 REFERENCES

2.1 The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
3395 : 1997	Low density polyethylene (LDPE) and linear low density polyethylene (LLDPE) materials for moulding and extrusion (*second revision*)
12418 (Part 3) : 1987	Intra-uterine contraceptive devices: Part 3 Packaging and labelling
13360 (Part 4/ Sec 1) : 1995	Plastics — Methods of testing: Part 4 Rheological properties: Section 1 Determination of the melt mass-flow rate (MFR) and the melt volume-flow rate (MVR) of thermoplastics

3 SHAPE AND DIMENSIONS

3.1 The shape and dimensions of Copper-T and its components shall be as shown in Fig. 1.

3.1.1 The flange as shown in Fig. 1 shall be positioned so as to be at 70 ± 5 mm from 'T' end on the insertion tube. The dimensions of the flange are for guidance only.

3.2 Mass of Copper Wire

The mass of copper wire wound on Copper-T shall be 124 ± 11 mg.

4 MATERIAL

4.1 'T'

The 'T' shall be made of a compound obtained by blending low density polyethylene (*see* IS 3395) and barium sulphate (20 to 24 percent) quality of $BaSO_4$, IP grade. The low density polyethylene material shall pass the extractables test when tested according to the method given in Annex A and shall have melt mass flow rate between 1.8 to 2.2 g/ten min when tested according to the method given in IS 13360 (Part 4/Sec 1).

NOTE — Suitable materials are Alathon 20 or 2005 manufactured by Dupoint, USA or equivalent.

4.1.1 The lower end of the vertical arm of the 'T' shall not deviate by more than 3 mm from the central axis.

4.2 Solid Rod

The solid rod shall be made of polypropylene with 0.5 ± .05 percent pharmaceutical grade titanium dioxide.

4.2.1 The solid rods with following shaped structure shall be acceptable:

a) Rod without having ball or fin,
b) Rod with ball, and
c) Rod with fin.

4.3 Insertion Tube

The insertion tube shall be made of high density polyethylene which shall pass the extractables test when tested according to the method given in Annex A. The polyethylene shall be tested at the manufacturing stage. It shall have a melt-mass flow rate between 0.6 to 0.8 g/ten min when tested according to the method given in IS 13360 (Part 4)/Section 1.

NOTE — Suitable material is Phillips Marlex 6006 or equivalent.

4.3.1 It is optional to have the marking of scale in cm on the insertion tube with a pharmaceutical grade material so that it does not produce any toxic effect when in contact with the body fluids.

4.4 Flange

The flange shall be made of polyvinyl chloride containing 1±.05 percent titanium dioxide and pharmaceutical grade 'blue' or 'yellow' (IP grade).

NOTE — Pharmaceutical grade 'blue' is a triphenylmethane group of dye. It is disodium salt of dibenzyldiamino-triphenyl-carbinol trisulphonic acid anhydride.

4.5 Tie (Thread)

The tie shall be made of high density polyethylene with 1±.05 percent titanium dioxide (IP grade) or iron oxide to give white or dark colour respectively. The material shall pass implantation test when tested according to the method given in Annex B.

NOTE — Suitable material is 'Phillips Marlex 6006' or equivalent.

4.6 Copper Wire

The material of copper wire shall be 99.99 percent pure and no other individual element shall be more than 50 ppm. The manufacturer shall ascertain the purity of the copper wire used.

5 REQUIREMENTS

5.1 The ends of the copper wire shall be round and shall not have any sharp point at the edges, and the end of the wire shall not protrude out.

5.2 The materials of which the 'T', insertion tube, solid rod, flange and tie are made shall be sufficiently resistant to unintended influence by the body fluids and tissues, and shall be biologically compatible without causing undue/unacceptable allergic, toxic or inflammatory reaction.

5.3 Copper-T, when inserted, shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

5.4 The 'T' shall be radio-opaque and shall have two ties for easy removal.

5.5 The tie or thread attached to the 'T' shall be monofilament which is easily feelable after insertion of the 'T'.

5.6 The 'T' when tested for flexibility and memory as described in **6.3** and **6.4**, shall have necessary viscoelastic properties to allow it to take up that form in the uterine cavity which it is intended to take.

5.7 Copper-T shall be free from sharp edges, rough surfaces and shall be finished smooth.

5.8 Copper-T shall be sterilized using an appropriate method and shall pass the sterility test given in **6.6**.

6 TESTS

6.1 Implantation Test

The 'T' and tie when subjected to implantation test as per the method given in Annex B shall not show reaction to more than one in four pieces significantly greater than that of the negative control implant.

6.2 Strength of Thread

Place the IUD in the tensile machine. The upper part of the IUD in the upper clamp and thread at a distance of 5 cm from the attachment of the lower clamp. Apply the force steadily at a separation speed of 3.3 ± 0.3 mm/s (200 ± 20 mm/min). The thread shall not come out of the 'T' or break at a load of less than 9.50 N.

6.3 Flexibility

The standard flexibility test measures the deflection in millimetres when a 20 g weight is applied to the horizontal arm of the 'T' for 30 seconds at a distance of 12 mm from the stem of the 'T'. 'T' units are subjected to test not earlier than 24 h after moulding and after at least 6 h of equilibration at 24 ± 1.5°C. Reading made at other temperatures within the range of 20 to 29°C may be corrected by subtracting 0.125 mm for each degree above 24°C and adding a similar amount for each degree below. Temperatures shall be constant within ±1.5°C for 6 h before reading. Not more than 5 of the 50 samples shall show a flexibility of less than 4.8 mm or more than 6.5 mm. None shall show a flexibility above 7.0 mm.

6.4 Memory

Memory is measured in terms of recovery after acute flexion. The horizontal arms are folded on the vertical arm and inserted, with the ball of the vertical arm leading, to a depth of 6.35 mm in a hole of 4.0 mm diameter. they are allowed to remain in this folded position for 5 min and then removed and allowed to recover their shape under zero load for one min. The recovery of the arms must be such that the tips of the arms are not displaced by more than 5 mm from the horizontal.

6.4.1 Sample 10 'T's at random from a batch. If the average recovery is greater than 5.5 mm from horizontal, reject the batch. If it is between 5.0 and 5.5 mm, sample another 10 units. Average of 20 shall be below 5.0 mm if the lot is to be accepted.

6.5 Ash Content

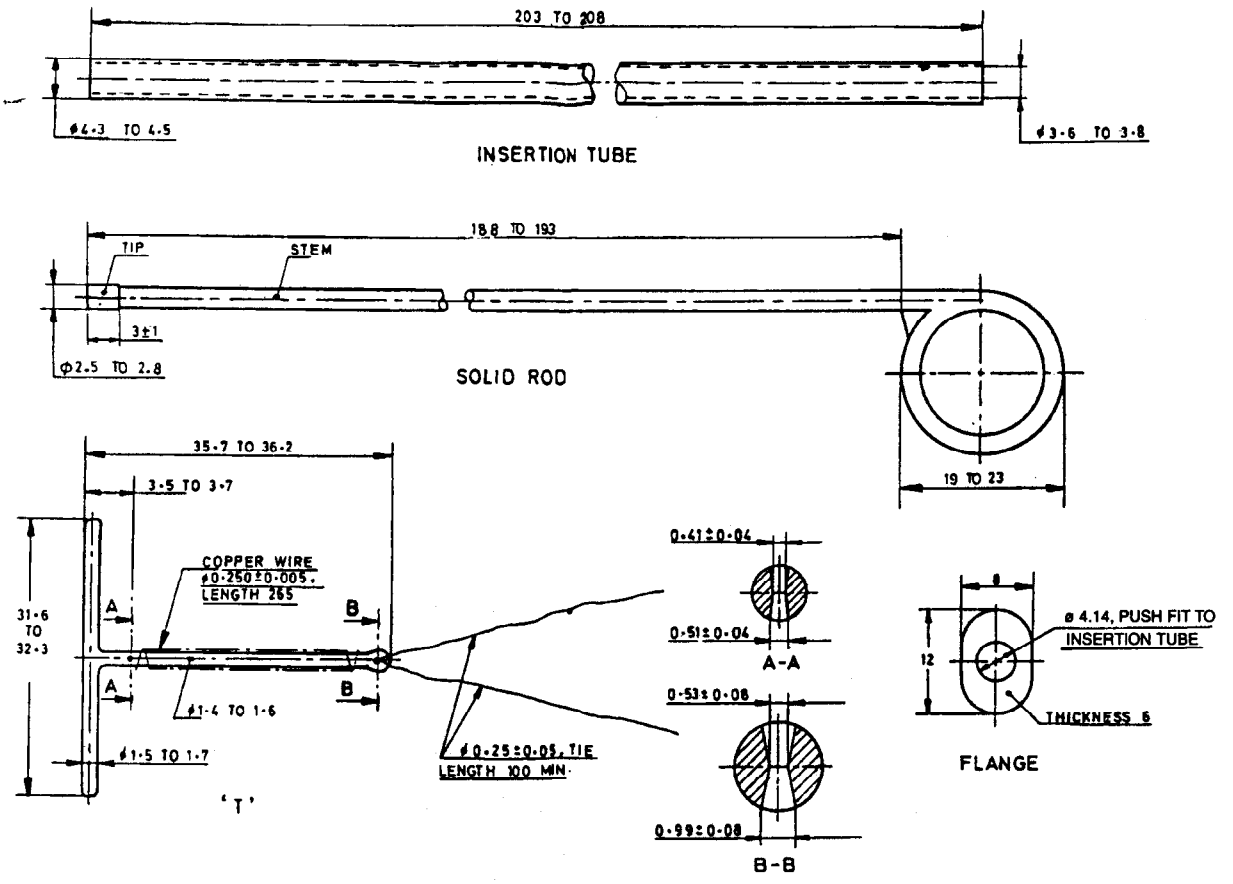
Ash content (as barium sulphate) of moulded 'T' shall be between 20 to 24 percent when tested in accordance with the method specified in the latest Indian Pharmacopoeia.

6.6 Sterility

It shall be capable of meeting the requirements of any suitable sterility test specified in the latest Indian Pharmacopoeia.

6.7 Pouch Peeling Force

The packing pouch shall peel off when a force of 700 to 1 700 g is applied on both the edges of the pouch at a speed of 250-300 mm/min.



FOR GUIDANCE ONLY

NOTES

1 The diameter of the stem of the solid rod shall be 0.2 mm less than that of its tip.

2 All dimensions shown in the figure shall be on finished product except that of the flange which is for guidance only.

3 The dimensions shall be measured either by go-no go gauges or by profile projector which should also be calibrated.

All dimensions in millimetres.

FIG. 1 COPPER-T

6.8 Flange Displacement Force

Flange selected at random is placed on the insertion tube selected at random and allowed to age in place for minimum 24 h. The resistance to displace the flange by a steadily applied force shall be between 180 to 630 g.

7 SAMPLING

7.1 Sampling and acceptance criteria for cu-T (200 B) shall be as given in Annex C.

8 PACKAGING AND LABELLING

8.1 The packaging and labelling shall conform to the requirements as given in IS 12418 (Part 3).

ANNEX A

(*Clauses* 4.1 *and* 4.3)

EXTRACTABLES TEST

A-1 APPARATUS

A-1.1 The apparatus for the test shall be as in **A-1.1.1** to **A-1.1.3**.

A-1.1.1 *Autoclave*

Use an autoclave capable of maintaining a temperature of 121.0±0.5°C equipped with a thermometer, a pressure gauge, a vent cock, a rack adequate to accommodate test containers above the water level, and a water cooling system that will allow for cooling of the test containers to about 22°C immediately following the heating cycle.

A-1.1.2 *Oven*

Use an oven, preferably a forced-circulation model, that will maintain operating temperatures of 50 or 70°C within ± 1°C.

A-1.1.3 *Extraction Containers*

Use containers, such as ampoules or screw-cap culture test tubes of borosilicate glass. If used, culture test tubes are closed with screw caps having suitable rubber liners, the exposed surface of the rubber liner is completely protected with an inert solid disc 0.05 to 0.075 mm in thickness. A suitable disc may be fabricated from a polytetrafluoro-ethylene resin.

A-1.2 Preparation of Apparatus

Clean all the glassware thoroughly with chromic acid cleansing mixture or if necessary, with hot nitric acid followed by prolonged rinsing with water. Clean the cutting devices by an appropriate method (for example, successive cleaning with acetone and methylene chloride) prior to use in sub-dividing a specimen. Clean all other equipment by thorough scrubbing with a suitable detergent and prolonged rinsing with water.

Render containers and devices used for extraction, and in transfer and administration of test material, sterile and dry by a suitable process.

NOTE — If ethylene oxide is used as sterilizing agent, allow adequate time for complete degassing.

A-2 PROCEDURE

A-2.1 Preparation of Sample

From a homogeneous plastic sample, use a portion equivalent to 120 cm^2 when the thickness is 500 m or less, or 60 cm^2 when the thickness is greater than 500 m. Subdivide into strips approximately 3 mm in width and as near to 50 mm in length as is practical. Remove particulate matter, such as, lint and free particles, by treating each subdivided sample as follows:

Transfer the subdivided sample to a clean, glass-stoppered 100 ml graduated cylinder of Type 1 glass (highly resistant borosilicate glass) and add about 70 ml of water for injection. Agitate for about 30 s and drain off the water.

A-2.2 Extracts

Place two properly prepared samples to be tested in separate extraction flasks and add to each flask, 20 ml of the appropriate extracting medium for parallel injections and comparison flask. Extract by heating in an oven at 70°C for 24 h. Allow adequate time for the liquid within the container to reach the extraction temperature. The contacts of the extracting medium are of importance with the available surface area of the plastic, the time and temperature during extraction, the proper cooling, agitation, and decanting process, and the handling and storage of the extracts following extraction.

Cool to about room temperature but not below 22°C, shake vigorously, and decant each extract, using aseptic precaution, into a dry, sterile vessel. Store the extracts at a temperature between 22 and 30°C and do not use for tests after 24 h.

A-2.3 Systemic Injection Test

This test is designed for the evaluation of extracts of a plastic material in mice.

A-2.4 Test Animal

Use healthy, not previously used albino mice weighing between 17 and 23 g. For each test group, use only mice of the same source. Offer water and food, commonly used for laboratory animals and known with respect to composition, *ad libitum*.

A-2.5 Procedure

Inject each extract of the sample and the corresponding blank, into groups of 5 mice each in the amount and by the route set forth in Table 1. Observe the animals immediately after injection, again 4 h after injection, and then not earlier than 24, 48 and 72 h, respectively after injection. If during the observation period none of the animals treated with the extract of the sample shows a significantly greater reaction than the animals treated with the blank, the sample meets the requirements of this test.

Table 1 Amount and Routes of Systemic Injection of Extracts and Blanks

(*Clause* 2.5)

Extract or Blank	Dose (per kg)	Injection	
		Route	Rate (ml/second)
Sodium chloride	50 ml	Intravenous	0.1
Sodium chloride injection (1 in 20 solution of sodium chloride in alcohol)	50 ml	Intravenous	0.1

NOTES

1 Agitate each extract vigorously prior to withdrawal of each injection dose to ensure even distribution of the extracted matter.

2 If any animal treated with the sample shows slight signs of toxicity, and not more than one animal shows gross symptoms of toxicity or dies, repeat the test using groups of 10 mice each. On the repeated test, the requirements of the test are met if none of the animals treated with the sample shows a significantly greater reaction than that observed in the animals treated with the blank.

A-3 INTRACUTANEOUS TEST

A-3.0 The test is designed for the evaluation of extracts of a plastic material in rabbits.

A-3.1 Test Animal

Select healthy, thin-skinned albino rabbits not previously used for any test. The fur of rabbit shall be clipped closely and the skin shall be free from mechanical irritation or trauma. In handling the animals, avoid touching the injection sites during observation period.

A-3.2 Procedure

On the day of the test, closely clip the fur on the animal's back on both sides of the spiral column over a sufficiently large test area. Avoid mechanical irritation and trauma. Remove loose hair means of vacuum. If necessary, swab the skin slightly with diluted alcohol, and dry the skin prior to injection.

Inject intracutaneously 0.2 ml of each extract of the sample at 10 sites on one side of each of two rabbits. Similarly, at five other sites on the other side of each rabbit, inject 0.2 ml of the corresponding blank. Examine the injected sites 24, 48 and 72 h after the injection for gross evidence of tissue reaction, such as, erythema, edema, aud eschar. To facilitate the examination, swab the skin lightly with diluted alcohol and clip the fur, if necessary. Rate the observation on a numerical scale for the extract of the sample and for the blank respectively using Table 2.

The average for the sample shall not be significantly greater than that for the blank.

Table 2 Evaluation of Skin Reactions

Sl No.	Nature of Reaction	Value
i)	Erythema and Eschar Formation No erythema	0
ii)	Very slight erythema (barely perceptible)	1
iii)	Well-defined erythema	2
iv)	Moderate to severe erythema	3
v)	Severe erythema (beet-redness) to slight eschar formation (injuries in depth)	4
vi)	Edema formation	
vii)	No edema	0
viii)	Very slight edema (barely perceptible)	1
ix)	Slight edema (edges of area well defined by definite raising)	2
x)	Moderate edema (raised approx 1 mm)	3
xi)	Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

NOTES

1 Agitate each extract vigorously prior to withdrawal of each injection dose, to ensure even distribution of the extracted matter.

2 If the result is doubtful, repeat the test using fresh extract in three more rabbits. The requirements of the test are met if on the repeated test the average for the extract of the sample is not significantly greater than that for the blank.

ANNEX B

(*Clauses* 4.5 *and* 6.1)

IMPLANTATION TEST

B-1 GENERAL

B-1.1 This method of test is designed to provide information on the effects of direct contact of a test material with the living tissues when implanted into the para-vertebral muscle of the rat/rabbit for a period of 14 days.

B-1.2 This method of test is for plastic materials which are intended for long term use (covers a period from a few months to permanent use) within the body tissue.

B-2 DEFINITIONS

B-2.1 Final Product

Medical device in its ready for use state.

B-2.2 Test Material

The final product or sample of final product that is to be tested.

B-2.3 Test Specimen

The piece of test material that is implanted.

B-2.4 Implant

The test specimen or negative control that has been implanted.

B-2.5 Implant Site

Implant four specimens into the para-vertebral muscle on one side of the spine of each animal, approximately not less than 20 mm from the mid-line and parallel to the spinal centre and about 25 mm apart from each other. There shall be not more than 5 mm of tissue surrounding it, measured from the centre of the implant.

B-2.6 Negative Control Specimen

A piece of material which when implanted by the procedure described in **B-5.2** produces a negative reaction (*see* **B-5.4.1.4**).

NOTE — Negative control standards are available from USP-NF Reference Standards 12601, Twinbrook Park-way, Rockville, Maryland 20852 USA or equivalent.

B-2.7 Device, Medical

Any item used in medical treatment, diagnosis or contraception, not intended to have a pharmacological reaction on the body.

B-3 ANIMALS AND HUSBANDRY

B-3.1 Two healthy adult rats/rabbits shall be selected whose paravertebral muscles are sufficiently large in size to allow for implantation of the test and negative control specimens, as described in **B-5.2**.

B-3.2 The animals shall be housed individually and shall have free access to food and water.

B-4 TEST AND CONTROL SPECIMENS

B-4.1 Number of Specimens Required

The minimum number of specimens for implantation in each rat/rabbit in accordance with **B-5.2**, shall be:

a) not fewer than two negative control specimens, and

b) not fewer than four test specimens.

NOTE — It may be necessary to implant more specimens than the minimum required because of loss, for example, by expulsion of implants during the 14-day test period.

B-4.2 Sterilization and Handling of Specimens

B-4.2.1 Test specimens for pre-sterilized devices and presterilized controls shall be asceptically handled.

B-4.2.2 All other test specimens shall be sterilized and shall be thereafter asceptically handled.

B-4.2.3 All other items used for the test shall be presterilized and shall be asceptically handled.

B-4.3 Preparation of Specimens

B-4.3.1 Immediately before implanting, cut the test material and the negative control material into specimens approximately 10 mm in length.

B-4.3.2 These cut specimens shall have smooth sides to minimize mechanical trauma during implantation.

B-4.3.3 After preparing and before implanting, place each specimen in a sterile solution containing 9 g per litre sodium chloride.

B-5 TEST PROCEDURE

B-5.1 Preparation of Animals

B-5.1.1 On the day of the test or up to 20 h before testing, clip the fur on the backs of the rats/rabbits on both sides of the spinal column close to the skin and swab the clipped area with antiseptic solution. Remove loose hair by means of vacuum, if necessary.

B-5.1.2 Perform the test in a clean area.

B-5.1.3 Anaesthetize the animal with a commonly used anaesthetic agent adequate enough to prevent muscular movements such as twitching.

NOTE — Anaesthetize the rats/rabbits by suitable injection, for example, 30 mg/kg pentabarbitone sodium intravenously.

B-5.1.4 Keep the record of the anaesthetic and the route of administration used.

B-5.2 Implantation of Specimens

B-5.2.1 Implant in one of the rats/rabbits, four test specimens and two negative control specimens.

B-5.2.2 Implantation shall be done in accordance with the procedure described in **B-5.2.3** to **B-5.2.8**.

B-5.2.3 Each implant shall be at least 25 mm away from any other implant.

B-5.2.4 Asceptically place into a sterile hypodermic needle having cannula length 19 to 35 mm and a bore of 1.8 mm.

B-5.2.5 Insert a sterile stylet behind the specimen in the needle.

B-5.2.6 Insert the needle vertically into the paravertebral muscle of the rat/rabbits.

B-5.2.7 Hold the stylet in place whilst the needle is gently withdrawn, leaving the stylet in place.

B-5.2.8 When the needle is free of the skin withdraw the stylet likewise, leaving the specimen implanted with the muscle.

B-5.2.9 Repeat the implantation in the second rat/rabbit.

B-5.3 Recovery of Implant Sites

B-5.3.1 After the implants have been in position for 14 days, sacrifice the rats/rabbits with an overdose of anaesthetic.

B-5.3.2 Place these rats/rabbits in the prone position with legs splayed.

B-5.3.3 Carefully excise the implant sites, leaving the implant in position.

B-5.4 Examination of Implant Sites

B-5.4.1 *Microscopic Examination*

B-5.4.1.1 Examine each excised implant site under normal vision or with the aid of a low magnification lens. Record the nature, extent and distribution of any tissue reaction observed.

B-5.4.1.2 If any negative control specimen evokes a reaction other than that described in **B-5.4.1.4**, the results for the test specimens in that rat/rabbits shall be rejected and the test repeated with another rabbit.

B-5.4.1.3 If any test specimen implant site shows a negative reaction (*see* **B-5.4.1.4**), all the test specimen implant sites and the negative control implant sites shall be removed for histological examination to confirm the response.

B-5.4.1.4 A reaction shall be considered a negative reaction if there is no reaction, or there is reaction that can be attributed to experimental trauma, typically asymmetrical, non-nectrotic and non-inflammatory.

B-5.4.1.5 If more than the minimum number of test specimens or negative control specimens are implanted, all of them shall be recovered.

B-5.4.1.6 All recovered specimens shall be considered as part of the test.

B-5.4.2 *Histological Examination*

B-5.4.2.1 Preserve the excised implant sites in formal saline.

B-5.4.2.2 Prepare sections transverse to the excised implants.

NOTES

1 Ideally, the implant should remain in place during preparation for sectioning to ensure correct orientation of the surrounding tissue unless adverse reaction with dehydrating or defatting solvents is likely to occur.

2 Hard implants may be removed before cutting of sections, if cutting would otherwise be difficult.

B-5.4.2.3 Stain the section with haemotoxylin and eosin.

B-5.4.2.4 Examine the histological sections microscopically and record the findings.

B-6 TEST RESULTS

B-6.1 The tissues surrounding negative control shall appear normal and entirely free from haemorrhage, film or encapsulation (*see* **B-5.4.1.4**).

B-6.2 The requirements of the test are met if, in each rat/rabbit, the reaction to not more than one of the four test specimens is significantly greater than that one of the negative control implant.

ANNEX C

(*Clause* 7.1)

C-1 LOT

All the cu-Ts of the same material and produced under similar conditions of manufacture shall be grouped together to constitute a lot. The lot shall however not exceed more than 35 000 pcs.

C-1.1 Unless otherwise agreed to between the purchaser and the supplier, the procedure given in IS 2500 (Part 1) 'Sampling inspection procedures: Part 1 Attribute sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspections (*second revision*)' shall be followed for sampling inspection. The inspection level, acceptable quality level (AQL) and type of sampling plan to be followed by various characteristics shall be as given in Table 3.

Table 3 Sampling Plan and AQL

Parameter	Defect Classification	Sampling Plan	AQL
i) Tee frame			
a) Length	minor	Single plan general inspection level I	4
b) Diameter	major	do	1.5
c) Flexibility			
Range	minor	Single plan	4
Upper limit	critical	special inspection level S-4	0.65
d) Memory	critical	As given in the test method	—
ii) Thread			
a) Length of tail	major	Single general inspection level I	2.5
b) Diameter	minor	do	4.0
c) Strength	critical	do	0.65
iii) Copper wire			
a) Weight	major	do	1
b) Purity	critical	As per standard test procedure	—
c) Wire protrusion	critical	Single plan general inspection level I	.01
iv) Tube			
a) Length	major	Single plan general	1
b) Internal diameter	do	inspection	1
c) Outer diameter	do	level I do	1
v) Displacement rod			
a) Length	major	Single plan general	1
b) Tip diameter	do	inspection level I	1
vi) Pouch peeling force	major	Single plan general inspection level I	1
vii) Sterility	critical	As per Indian Pharmacopoeia	—
viii) Implantation	do	do	—

C-1.2 Relevant extracts from Table I and Table II-A as given in IS 2500 (Part I) are reproduced in Tables 4 and 5 respectively.

Table 4 Sample Size Code Letters

Lot of Batch Size	Special Inspection Level S-4	General Inspection Level I
2 to 8	A	A
9 to 15	A	A
16 to 25	B	B
26 to 50	C	C
51 to 90	C	C
91 to 150	D	D
151 to 280	E	E
281 to 500	E	F
501 to 1 200	F	G
1 201 to 3 200	G	H
3 201 to 10 000	G	J
1 0 001 to 35 000	H	K

Table 5 Single Sampling Plans for Normal Inspection

Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)						
		0.010	0.10	0.65	1.0	1.5	2.5	4.0
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
A	2	↓	↓	↓	↓	↓	↓	↓
B	3	↓	↓	↓	↓	↓	↓	0 1
C	5	↓	↓	↓	↓	↓	0 1	↑
D	8	↓	↓	↓	↓	0 1	↑	↓
E	13	↓	↓	↓	0 1	↑	↓	1 2
F	20	↓	↓	0 1	↑	↓	1 2	2 3
G	32	↓	↓	↑	↓	1 2	2 3	3 4
H	50	↓	↓	↓	1 2	2 3	3 4	5 6
J	80	↓	↓	1 2	2 3	3 4	5 6	7 8
K	125	↓	0 1	2 3	3 4	5 6	7 8	10 11
L	200	↓	↑	3 4	5 6	7 8	10 11	14 15
M	315	↓	↓	5 6	7 8	10 11	14 15	21 22
N	500	↓	1 2	7 8	10 11	14 15	21 22	↑
P	800	↓	2 3	10 11	14 15	21 22	↑	↑
Q	1 250	0 1	3 4	14 15	21 22	↑	↑	↑
R	2 000	↑	5 6	21 22	↑	↑	↑	↑

↓ = Use first sampling plan below arrow: If sample size equals, or exceeds, lot or batch size, carry out 100% inspection.

↑ = Use first sampling plan above arrow.

Ac = Acceptance number

Re = Rejection number

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